

PCT

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT



(PCT Article 36 and Rule 70)

10/530073

Applicant's or agent's file reference AM-101125		<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/EP 03/11360	International filing date (day/month/year) 14.10.2003	Priority date (day/month/year) 15.10.2002	
International Patent Classification (IPC) or both national classification and IPC C12Q1/68			
Applicant WYETH et al.			

1. This International preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.  
  
☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).  
  
These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:
  - I ☒ Basis of the opinion
  - II ☐ Priority
  - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
  - IV ☐ Lack of unity of invention
  - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
  - VI ☐ Certain documents cited
  - VII ☐ Certain defects in the international application
  - VIII ☐ Certain observations on the international application

Date of submission of the demand  10.05.2004	Date of completion of this report  03.12.2004
Name and mailing address of the international preliminary examining authority:   European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer  Brochado Garganta, M  Telephone No. +49 89 2399-8935  

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/EP 03/11360

**I. Basis of the report**

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*):

**Description, Pages**

1-37 as originally filed

**Claims, Numbers**

1-21 as originally filed

**Drawings, Sheets**

1/11-11/11 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).  
☐ the language of publication of the international application (under Rule 48.3(b)).  
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☒ contained in the international application in written form.  
☒ filed together with the international application in computer readable form.  
☐ furnished subsequently to this Authority in written form.  
☐ furnished subsequently to this Authority in computer readable form.  
☒ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.  
☒ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:  
☐ the claims, Nos.:  
☐ the drawings, sheets:

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5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Yes: Claims	1-21
	No: Claims	
Inventive step (IS)	Yes: Claims	1-21
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-21
	No: Claims	

**2. Citations and explanations**

**see separate sheet**

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**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability;  
citations and explanations supporting such statement**

1. Reference is made to the following documents:

(D1) Irit Davidson et al. Avian Pathology, vol. 31, 2002, pages 237-240

2. Novelty

The subject-matter of claim 1, relating to a method for detecting a virus in an avian tissue sample, is new in the sense of Article 33(2) PCT, because a method wherein the sample is derived from feathers of the axillary tract is not disclosed in the prior art.

For the same reasons, dependent claims 2-16, and claims 17-21, relating to an isolated avian tissue sample and a genetic material-containing extract, are also novel (Article 33(2) PCT).

3. Inventive step

D1 discloses a method of detecting a virus in a sample, wherein the genetic material is extracted from the tips of wing feathers, liver and spleen. It is determined that using DNA from feather tips was more effective for diagnosis of naturally infected commercial chickens than using the liver and spleen (see pages 237-238 and table 1).

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The difference between the subject-matter of claim 1 and the disclosure in D1 is the fact that the genetic material is extracted from feathers from the axillary tract.

The problem to be solved by the present application is to provide an improved method for detection of a virus in an avian tissue sample.

Avian virus can be detected in axillary tract feathers at higher levels than in other feathers and therefore it can be detected in axillary tract feathers according to the invention when it cannot be detected in other tissue samples, including other feathers. At 13 days after vaccination, the mean virus load for the chicks is up to four-fold greater in the axillary tracts than in the other feather tracts (see pages 3 and 4, and figure 10b of the present application).

Nothing in D1 would lead the skilled person to think that the sensitivity of the method could be increased by using feathers from the axillary tract. Thus, claim 1 is considered to involve an inventive concept as required by Article 33(3) PCT.

The same seems to apply to dependent claims 2-16, and claims 17-21, relating to an isolated avian tissue sample and a genetic material-containing extract, which are also not disclosed in the prior art and are capable of being used in the claimed method, leading to an increased sensitivity of the same. These claims could also be considered as inventive (Article 33(3) PCT).

#### 4. Clarity

- 4.1 Claims 15 and 16 are not clear (Article 6 PCT), as the claimed features, i.e. furnishing the results of the method in an intelligible format, and recording or storing the results of the method on an information carrier, are not characterising features of the method.

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4.2 Claims 17 and 19 are not clear (Article 6 PCT), because the claimed avian tissue sample is not characterised by means of technical features.

4.3 Claims 20 and 21 are not clear (Article 6 PCT), as the claimed features, i.e. storing the sample or extract in a form suitable for transport to a separate location, and having the sample or extract in a sealed container, are not characterising features of the sample neither of the extract.